

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS <i>Offeror to complete blocks 12, 17, 23, 24, & 30</i>				1. REQUISITION NUMBER		PAGE 1 OF 29									
2. CONTRACT NO.		3. AWARD/EFFECTIVE DATE		4. ORDER NUMBER		5. SOLICITATION NUMBER RFP-BARDA-08-12		6. SOLICITATION ISSUE DATE							
7. FOR SOLICITATION INFORMATION CALL		A. NAME LTJG Leon C. Snyder				B. TELEPHONE (<i>No Collect Calls</i>) 202-260-1720		8. OFFER DUE DATE/LOCAL TIME 03/10/2008 11:00AM EST							
9. ISSUED BY DHHS/ASPR/BARDA 330 Independence Avenue, SW Rm. G640 WASHINGTON DC 20201 Attention: Darrick A. Early, Contracting Officer				CODE		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED <input type="checkbox"/> SET-ASIDE: % FOR <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> SMALL DISADV. BUSINESS <input type="checkbox"/> 8(A) NAICS: 541712 SIZE STANDARD: 750		11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input type="checkbox"/> SEE SCHEDULE <input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) 13b. RATING 14. METHOD OF SOLICITATION <input type="checkbox"/> RFQ <input type="checkbox"/> IFB <input checked="" type="checkbox"/> RFP							
15. DELIVER TO: SEE SOO FOR DELIVERY INFORMATION				CODE		16. ADMINISTERED BY SEE BLOCK 9									
17a. CONTRACTOR/OFFEROR TELEPHONE: <input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				CODE		FACILITY		18a. PAYMENT WILL BE MADE BY SEE BLOCK 9 EFT: T							
18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED: <input type="checkbox"/> SEE ADDENDUM				CODE											
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES				21. QUANTITY		22. UNIT		23. UNIT PRICE		24. AMOUNT			
		TITLE: Acquisition of palatability studies for masking the respective tastes of ciprofloxacin and doxycycline when prepared for oral suspension at home during a public health emergency; and of evaluation studies of home preparation instructions for said oral suspensions. <i>(Attach Continuation Sheet as Necessary)</i>								SEE PAGE 2 FOR SCHEDULE					
25. ACCOUNTING AND APPROPRIATION DATA								26. TOTAL AWARD AMOUNT (<i>For Govt. Use Only</i>)							
<input checked="" type="checkbox"/> 27a. SOLICITATIONS INCORPORATE BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA <input checked="" type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED. <input type="checkbox"/> 27b. CONTRACTS/PURCHASE ORDERS INCORPORATE BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED.															
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN <u>3</u> COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.						29. AWARD OF CONTRACT: REFERENCE _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: <input type="checkbox"/>									
30a. SIGNATURE OF OFFEROR/CONTRACTOR						31a. UNITED STATES OF AMERICA (<i>SIGNATURE OF CONTRACTING OFFICER</i>)									
30b. NAME AND TITLE OF SIGNER (<i>TYPE OR PRINT</i>)				30c. DATE SIGNED		31b. NAME OF CONTRACTING OFFICER Darrick A. Early				31c. DATE SIGNED					
32a. QUANTITY IN COLUMN 20 HAS BEEN <input type="checkbox"/> RECEIVED <input type="checkbox"/> INSPECTED <input type="checkbox"/> ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED						33. SHIP NUMBER <table border="1"><tr><td></td><td>PARTIAL</td><td></td><td>FINAL</td></tr></table>			PARTIAL		FINAL	34. DO VOUCHER NUMBER		35. AMOUNT VERIFIED CORRECT FOR	
	PARTIAL		FINAL												
32b. SIGNATURE OF AUTHORIZED GOVT. REPRESENTATIVE						32c. DATE		36. PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL							
41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT						38. S/R ACCOUNT NUMBER		39. S/R VOUCHER NUMBER		40. PAID BY					
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER						41c. DATE		42a. RECEIVED BY (<i>Print</i>)							
						42b. RECEIVED AT (<i>Location</i>)									
						42c. DATE REC'D (<i>YY/MM/DD</i>)		42d. TOTAL CONTAINERS							

CONTINUATION SHEET		REFERENCE NO. OF DOCUMENT BEING CONTINUED RFP-BARDA-08-12		PAGE 2	
NAME OF OFFEROR OR CONTRACTOR					
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	SECTION B—SUPPLIES/SERVICES Phase I Palatability studies See Contract Objective 1.1.1 (Item 0002 is an option that may be exercised by the Government during the period from award to 18 months after award depending on results from Phase I studies)	1	1		
0002	Phase II Home Preparation Instructions See Contract Objective 1.2.1 Optional line item dependent upon acceptable findings from Phase I	1	1		

NSN 7540-01-152-8067

OPTIONAL FORM 336 (4-86)
Sponsored by GSA
FAR (48 CFR) 53.11

Section A – Solicitation/Contract/Order for Commercial Items (SF 1449)

Section B – Supplies/Services

Section B1. Brief description of supplies or services

Acquisition of palatability studies for masking the respective flavors of ciprofloxacin and doxycycline when prepared for oral suspension at home during a public health emergency; and of evaluation studies of home preparation instructions for said oral suspensions.

Section B2. Optional Purchases

The Biomedical Advanced Research and Development Authority (BARDA) may exercise optional line item 0002 up to 18 months after award dependent on the results of line item 0001.

Section C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

Section C1. Background

Following the 2001 anthrax mail attacks, the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) became concerned about the lack of availability of pediatric formulations of ciprofloxacin and doxycycline should another anthrax attack occur. Therefore, CDER began to develop emergency home preparation instructions for pediatric use of these drugs. Early in the instruction development process, CDER recognized that stability, dose uniformity, and palatability data were crucial to the effectiveness of home preparation instructions; and, for that reason, CDER staff conducted several studies in support of emergency home preparation instructions. CDER staff tested and evaluated the data from solid oral dosage formulations of doxycycline and ciprofloxacin, respectively, when mixed with various household foods and drinks. Each drug mixed with food/drink was rated for palatability; however, absolute palatability for each mixture was not measured. In light of these laboratory studies, CDER posted doxycycline emergency home preparation instructions for anthrax prophylaxis on its external website in 2002. These instructions were intended to assist the layperson during an emergency in taking solid oral dosage forms of doxycycline and converting them to child-friendly, liquid, oral dosage forms using commonly-available household materials. In 2005, it was decided by emergency response subject matter experts at the Centers for Disease Control and Prevention that the instructions developed from this 2001 initiative were to be included as a component of the MedKit.

Section C2. Statement of Objectives (SOO)

Independently, and not as an agent of the United States Government (USG), the contractor shall furnish all necessary services, qualified personnel, materials, supplies, equipment, facilities, transportation, and travel not otherwise provided by the USG as required to conduct the following:

C2.1 Program Objectives

The first objective for this contract is to design and conduct palatability studies of doxycycline and ciprofloxacin, respectively, and to provide a rationale or

justification for the foodstuffs selected for testing. The final objective of the palatability studies is to identify foods, pharmaceutical flavoring additives, and/or instruction procedures that will most successfully mask the unpleasant taste of ciprofloxacin and doxycycline solid oral dosage forms intended to be used in pediatric, dysphagic, and elderly populations during an anthrax emergency.

The second objective is to design and conduct studies to evaluate home preparation instructions of the respective compounding procedures for doxycycline and ciprofloxacin in medical kits. The final objective for the home preparation studies should be to evaluate performance of the home preparation instructions when performed in a household by laypersons.

C2.2 Contract Objectives

C2.2.1 Phase I - Palatability Studies (Line Item 0001)

Palatability studies to include selecting and testing of common food substances and potential pharmaceutical flavoring additives to prepare liquid oral dosages of ciprofloxacin and doxycycline, respectively, for pediatric, dysphagic, and elderly persons. The substances to be tested should include those already studied and/or listed in the current FDA ciprofloxacin and doxycycline home preparation instruction guide as well as food substances and possible pharmaceutical flavoring additives not currently listed that may be used for taste-masking, respectively, of ciprofloxacin and doxycycline as evidenced by palatability studies.

The following should be carried out as part of the palatability studies:

- Assessment of alternative preparation instructions that may increase palatability (following evaluation of FDA's draft home preparation instructions that will be supplied to the contractor).
- Evaluation of baby formula(s) as one of the food substances for administering doxycycline and ciprofloxacin. Compounding with baby formula may be more suitable for children less than 2 years old. A proposal should be included on the feasibility of this assessment.
- Determination of other candidate foods to test in addition to foods already studied.
 - Food substances previously studied in home preparations for doxycycline include: water, simple syrup with sour apple flavor, apple juice with sugar, low fat milk, low fat chocolate milk, regular chocolate milk, chocolate pudding, grape jelly, strawberry jelly, and yogurt with cherry flavor.
 - Food substances previously studied in home preparations for ciprofloxacin include: water, apple juice, low fat chocolate milk, imitation maple syrup, strawberry jam, and chocolate syrup.

- Determination of commercial pharmaceutical flavoring additives as alternatives to foodstuffs.

As it has been difficult to achieve adequate palatability for ciprofloxacin, creative problem solving is strongly encouraged.

C.2.2.2 Phase II - Home Preparation Studies (Optional Line Item 0002)

Once the most acceptable palatable options are identified for doxycycline and ciprofloxacin, respectively, the evaluation of Home Preparation instructions (using household supplies) will be initiated with the identified substances. The following studies and/or reports will be required:

- Perform and report results from studies that evaluate performance of the home preparation instructions developed for doxycycline and ciprofloxacin, respectively.
- Assess and report results of ability to follow and adhere to preparation instructions.
- Assess and report results of appropriateness of proposed preparation method(s) of doxycycline or ciprofloxacin, respectively, when employed by a layperson. For example, does formulation adequately soften when soaked in water for 5 minutes? Would encapsulation facilitate the process? Can the solid oral dosage form supplied to the test subject be mixed successfully and then suspended uniformly in the desired food or flavoring matrix?
- Assess and report results of dose uniformity testing.
- Assess and report results of dose recovery testing.
- Assess and report results of ability to deliver the intended dose when mixed with the recommended foods substances for the stated period of time.
- Assess and report results of information relating to drug's stability in the selected food substances.

Advise and report on the quality assurance surveillance plan.

C2.3 REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit a monthly Technical Progress Report to the Contracting Officer and the Project Officer. Each Technical Progress Report shall be due on or before the 15th of the month following each monthly reporting period. The first reporting period consists of the first full calendar month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. A Technical Progress Report will not be required for the period when the Final Report is due.

C2.3.1 Monthly Technical Progress Reports shall include:

- An executive summary of all contractor work performed that covers the work accomplished during each reporting period as established by the Project Officer. The executive summary shall include the following:
 - Title page containing Title, the contract number and title, the period of performance or milestone being reported, the contractor's name, and the date of submission;
 - Project Progress presented as talking point bullets and including milestone events, test results, tasks, and other activities achieved during the reporting period.
- Project Issues presented as headings and each item as a talking point bullet
- All direct costs by line item
- An assessment of technical progress
- Schedule status
- Any travel conducted
- Any Contractor concerns or recommendations for the previous period
- An estimate of work to be completed in the subsequent reporting period shall also be included in the report
- The Project Officer shall review each Technical Progress Report and shall notify the Contractor, within 30 days of receipt, of acceptance or of needed changes or problems.

C2.3.2 FINAL TECHNICAL REPORT

The Contractor shall submit two (2) copies and an electronic copy of the Final Technical Report. The Final Technical Report shall be submitted on or before the completion date of the contract and shall consist of the work performed and the results obtained for the entire contract period of performance. The Final Technical Report shall be in sufficient detail to describe comprehensively the results achieved and shall include pertinent data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from the analysis, and a scientific evaluation of the data accrued under the contract. A draft Final Technical Report shall be submitted to the Project Officer for review and revision, as needed. The Contractor shall submit to the Project Officer and Contracting Officer the original, three copies, and the electronic copy of the Final Technical Report with revisions. A Monthly or Annual Report shall not be required for the period when the Final Report is due.

Technical Report Distribution List for Monthly and Final Reports

Item	Type of Report	Distribution of Copies	Due Date
1.	Monthly Technical Progress Report	Original – C.O. 1 Copy – P.O.	Due on/before the 15 th of the month following each monthly reporting period.
2.	Final Technical Progress	Original – C.O. 1 Copy – P.O.	Due on/before the contract completion date.
3.	Summary of Salient Results	Original – C.O. 1 Copy – P.O.	Due with the Final Report.

Section C3. Meetings and Conferences

The Contractor shall participate in a monthly conference call and other calls to be arranged by the Project Officer (Contracting Officer's Technical Representative) as deemed necessary to coordinate and oversee the contracting effort. Such conference calls may include, but are not limited to, technical, regulatory, and ethical aspects of the program.

Section D - RESERVED

Section E - RESERVED

Section F - DELIVERIES OR PERFORMANCE

Section F1. Deliverables

F1.1 Phase I - Palatability Studies – Deliverables (Line Item 0001)

- Written report on palatability studies indicating successful food substances or possible pharmaceutical flavoring additives and testing methodologies used to identify those which provide successful masking.
- All raw study data as well as monthly technical reports and final summary reports that include the recommended readily available household food substances and/or instruction procedures which most successfully masked the after-taste of ciprofloxacin and doxycycline.
- All raw data and final summary reports shall be provided in an electronic format that can easily be navigated as well as in a well-organized hard copy format.
- Verbatim standard operating procedures (stepwise approach) used for carrying out testing of studies and all contractor work performed.
- Spreadsheet format of all costs including estimations for conducting palatability studies and studies for evaluating home preparation instructions.

Spreadsheet shall be easy to understand and be accompanied with adequate explanations, e.g., where instructions already exist regarding mixing, such as pharmaceutical flavoring.

- Written assessment of studies done or planned, including hypothesis, testing methods, references, and timeline.

F1.2 Phase II - Home Preparation Studies – Deliverables (Optional Line 0002)

- Written report of each of the requirements outlined under Section C2.2.2 for the evaluation of home preparation instructions of successfully identified food substances and/or pharmaceutical flavoring additives.
- Written reports of available dose uniformity data, recovery, and interaction studies of foods found to have acceptable availability and palatability.
- All raw study data as well as monthly technical reports and final summary reports that include the recommended readily available household food substances and/or instruction procedures (identified in Phase I) which most successfully masked the after-taste of ciprofloxacin and doxycycline, respectively.
- All raw data and final summary reports shall be provided in an electronic format that can easily be navigated as well as in a well-organized hard copy format.
- Verbatim standard operating procedures (stepwise approach) used for carrying out testing of studies and all contractor work performed.
- Spreadsheet format of all costs including estimations for conducting palatability studies and studies for evaluating home preparation instructions. Spreadsheet shall be easy to understand and be accompanied with adequate explanations (e. g. Where instructions already exist regarding mixing such as pharmaceutical flavoring)
- Written assessment of studies done or planned including hypothesis, testing methods, references and timeline.

F.2. Period of Performance – To be determined dependent on negotiated milestones

SECTION G - RESERVED

SECTION H - RESERVED

SECTION I – CONTRACT CLAUSES

Section II. Commercial Item Clauses - Incorporated by Reference

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

52.212-1, Instructions to Offerors-Commercial Items (Sep 2006)

52.212-4, Contract Terms and Conditions-Commercial Items (Feb 2007)

I.2. 52.212-1-Addendum

- a. Central Contractor Registry (CCR) registration must be up to date. Failure to register in the CCR will result in ineligibility for award. (Visit www.ccr.gov to initiate registration.)
- b. Proposal must include documentation adequate to support the proposed prices. This may include published price lists, catalog pricing, or any other information that can be used to determine that quoted prices are fair and reasonable. Per FAR 15.403-3, if the contracting officer is unable to determine, using a price analysis, that the price is fair and reasonable, information other than cost and pricing data will be requested.
- c. Technical proposal should conform to the instructions listed in Attachment 2 and must not exceed 100 pages.
- d. Offeror must submit six (6) copies of technical proposals and three (3) copies of business proposals to the address identified in block 9 of the 1449 by the closing date and time. Proposals should be independent of one another and be easily evaluated simultaneously. Each technical proposal should include a CD-ROM or other electronic media containing all proposal information. Technical proposals must not include cost or price information. Fax copies of proposals will not be accepted.
- e. Proposed unit prices **must include all applicable costs** and supporting documentation.
- f. Award will be based on the offeror's demonstrated ability to meet all requirements of the RFP. Award will not be made without a determination that the Government is receiving a fair and reasonable price.
- g. All questions must be submitted in writing to Darrick A. Early at darrick.early@hhs.gov and LTJG Leon C. Snyder at leon.snyder@hhs.gov.

I. 3. 52.212 -4 Addendum

A. PACKAGING

Reserved

B. CONTRACTING OFFICER

(1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

(2) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

C. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

D. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

I.4. 52.212-2 Evaluation – Commercial Items (Jan 1999)

(a) The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of

all factors other than cost or price. In any event, the Government reserves the right to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government. The following factors shall be used to evaluate offers:

Evaluation Criteria	Points
1. Feasibility of the Approach	70
2. Personnel/Management	30
TOTAL	100

A. Feasibility of the Approach

Weight: 70

1) Palatability Studies

- i) Demonstrated ability to successfully identify food substances and/or pharmaceutical flavoring additives that best mask the respective tastes of doxycycline and ciprofloxacin.
- ii) Demonstrated ability (e.g., using ranking methods or statistical analyses) to quantitate palatability results of the targeted population so that objective ranking of foodstuffs can be performed.
- iii) Demonstrated ability to conduct human panel studies among the targeted population suitable for evaluation of palatability.
- iv) Demonstrated experience in the areas of budgets and administrative procedures.

2) Home Preparation Studies

- i) Demonstrated ability to successfully perform and report results that evaluate execution of the home preparation instructions developed respectively for doxycycline and ciprofloxacin, including creative problem solving.
- ii) Demonstrated experience in the areas of budgets and administrative procedures.

B. Personnel/Management

Weight: 30

- 1) Documented availability, qualifications, experience, education, and competence of professional, technical, and other personnel to include any proposed subcontractors and/or consultants that will be assigned to work on this contract.
- 2) Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of a management structure with the capacity to respond to high-level, short time-frame requests.

TOTAL: 100

C. Past Performance

Past Performance - The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance. The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance. The Government will evaluate the offeror's past performance based on information obtained from references provided by the offeror, other relevant past performance information obtained from

other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

Listed below are past performance subfactors and the ratings to be used for evaluation purposes.

- a. Quality of Service - Record of conforming to specifications and to standards of good workmanship;
- b. Cost Control - Record of forecasting and controlling costs;
- c. Timeliness of Performance - Adherence to contract schedules, including the administrative aspects of performance;
- d. Business Relations - Reputation for reasonable and cooperative behavior and commitment to adherence to contract requirements;
- e. Customer Satisfaction - Concern for the interest of the Customer.

Past Performance Subfactors Rating Scale: (Poor, Average, Excellent)

Poor	Based on the Offeror's performance record, serious doubt exists that the Offeror will successfully perform the required effort. Sources of information consistently stated that the Offeror's performance was entirely unsatisfactory and that they would not do business with the Offeror again.
Average	Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is average or that favorable reports are offset by unfavorable reports.
Excellent	Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.

I.5. 52.212-3 Offeror Representations and Certifications-Commercial Items (November 2006).

An offeror shall complete only paragraph (j) of this provision if the offeror has completed the annual representations and certifications electronically at <http://orca.bpn.gov>. If an offeror has not completed the annual representations and certifications electronically at the ORCA website, the offeror shall complete only paragraphs (b) through (i) of this provision.

(a) *Definitions*. As used in this provision:

“Emerging small business” means a small business concern whose size is no greater than 50 percent of the numerical size standard for the NAICS code designated.

“Forced or indentured child labor” means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

“Service-disabled veteran-owned small business concern”—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

“Small business concern” means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

“Veteran-owned small business concern” means a small business concern—

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

“Women-owned business concern” means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

“Women-owned small business concern” means a small business concern—

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(b) *Taxpayer Identification Number (TIN)* (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to a central contractor registration database to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (b)(3) through (b)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror’s relationship with the Government (31 U.S.C. 7701(c) (3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror’s TIN.

(3) *Taxpayer Identification Number (TIN)*.

- o TIN: _____.
- o TIN has been applied for.
- o TIN is not required because:

- o Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;
- o Offeror is an agency or instrumentality of a foreign government;
- o Offeror is an agency or instrumentality of the Federal Government.

(4) *Type of organization.*

- o Sole proprietorship;
- o Partnership;
- o Corporate entity (not tax-exempt);
- o Corporate entity (tax-exempt);
- o Government entity (Federal, State, or local);
- o Foreign government;
- o International organization per 26 CFR 1.6049-4;
- o Other _____.

(5) *Common parent.*

- o Offeror is not owned or controlled by a common parent;
- o Name and TIN of common parent:
Name _____.
TIN _____.

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) *Small business concern.* The offeror represents as part of its offer that it o is, o is not a small business concern.

(2) *Veteran-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it o is, o is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern.* [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c) (2) of this provision.] The offeror represents as part of its offer that it o is, o is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c) (1) of this provision.] The offeror represents, for general statistical purposes, that it o is, o is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(5) *Women-owned small business concern.* [Complete only if the offeror represented itself as a small business concern in paragraph (c) (1) of this provision.] The offeror represents that it o is, o is not a women-owned small business concern.

Note: Complete paragraphs (c) (6) and (c) (7) only if this solicitation is expected to exceed the simplified acquisition threshold.

(6) *Women-owned business concern (other than small business concern).* [Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c) (1) of this provision.] The offeror represents that it o is a women-owned business concern.

(7) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:

(8) *Small Business Size for the Small Business Competitiveness Demonstration Program and for the Targeted Industry Categories under the Small Business Competitiveness Demonstration Program.* [Complete only if the offeror has represented itself to be a small business concern under the size standards for this solicitation.]

(i) [Complete only for solicitations indicated in an addendum as being set-aside for emerging small businesses in one of the designated industry groups (DIGs).] The offeror represents as part of its offer that it o is, o is not an emerging small business.

(ii) [Complete only for solicitations indicated in an addendum as being for one of the targeted industry categories (TICs) or designated industry groups (DIGs).] Offeror represents as follows:

(A) Offeror's number of employees for the past 12 months (check the Employees column if size standard stated in the solicitation is expressed in terms of number of employees); or

(B) Offeror's average annual gross revenue for the last 3 fiscal years (check the Average Annual Gross Number of Revenues column if size standard stated in the solicitation is expressed in terms of annual receipts).

(Check one of the following):

Number of Employees Average Annual Gross Revenues

<input type="checkbox"/> 50 or fewer	<input type="checkbox"/> \$1 million or less
<input type="checkbox"/> 51–100	<input type="checkbox"/> \$1,000,001–\$2 million
<input type="checkbox"/> 101–250	<input type="checkbox"/> \$2,000,001–\$3.5 million
<input type="checkbox"/> 251–500	<input type="checkbox"/> \$3,500,001–\$5 million
<input type="checkbox"/> 501–750	<input type="checkbox"/> \$5,000,001–\$10 million
<input type="checkbox"/> 751–1,000	<input type="checkbox"/> \$10,000,001–\$17 million
<input type="checkbox"/> Over 1,000	<input type="checkbox"/> Over \$17 million

(9) [Complete only if the solicitation contains the clause at FAR 52.219-23, *Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns*, or FAR 52.219-25, *Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting*, and the offeror desires a benefit based on its disadvantaged status.]

(i) *General.* The offeror represents that either—

(A) It o is, o is not certified by the Small Business Administration as a small disadvantaged business concern and identified, on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration (PRO-Net), and that no material change in disadvantaged ownership and control has occurred since its certification, and,

where the concern is owned by one or more individuals claiming disadvantaged status, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); or

(B) It o has, o has not submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(ii) o *Joint Ventures under the Price Evaluation Adjustment for Small Disadvantaged Business Concerns*. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements in 13 CFR 124.1002(f) and that the representation in paragraph (c)(9)(i) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. [*The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.*]

(10) *HUBZone small business concern*. [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.*] The offeror represents, as part of its offer, that—

(i) It o is, o is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR Part 126; and

(ii) It o is, o is not a joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. [*The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture: _____.*] Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Representations required to implement provisions of Executive Order 11246—

(1) Previous contracts and compliance. The offeror represents that—

(i) It o has, o has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation; and

(ii) It o has, o has not filed all required compliance reports.

(2) *Affirmative Action Compliance*. The offeror represents that—

(i) It o has developed and has on file, o has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 cfr parts 60-1 and 60-2), or

(ii) It o has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions (31 U.S.C. 1352)*. (Applies only if the contract is expected to exceed \$100,000.) By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to

any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract.

(f) *Buy American Act Certificate*. (Applies only if the clause at Federal Acquisition Regulation (FAR) 52.225-1, Buy American Act—Supplies, is included in this solicitation.)

(1) The offeror certifies that each end product, except those listed in paragraph (f)(2) of this provision, is a domestic end product and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products. The terms “component,” “domestic end product,” “end product,” “foreign end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American Act—Supplies.”

(2) Foreign End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(3) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(g)(1) *Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate*. (Applies only if the clause at FAR 52.225-3, Buy American Act—Free Trade Agreements—Israeli Trade Act, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(1)(ii) or (g)(1)(iii) of this provision, is a domestic end product and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The terms “component,” “domestic end product,” “end product,” “foreign end product,” and “United States” are defined in the clause of this solicitation entitled “Buy American Act—Free Trade Agreements—Israeli Trade Act.”

(ii) The offeror certifies that the following supplies are end products of Australia, Canada, Chile, Mexico, or Singapore, or Israeli end products as defined in the clause of this solicitation entitled “Buy American Act—Free Trade Agreements—Israeli Trade Act”:

End Products of Australia, Canada, Chile, Mexico, or Singapore or Israeli End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iii) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (g)(1)(ii) of this provision) as defined in the clause of this solicitation entitled “Buy American Act—Free Trade Agreements—Israeli Trade Act.” The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products:

Line Item No.	Country of Origin
---------------	-------------------

_____	_____
_____	_____
_____	_____

[List as necessary]

(iv) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25.

(2) *Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate, Alternate I (Jan 2004)*. If Alternate I to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled “Buy American Act—Free Trade Agreements—Israeli Trade Act”:

Canadian End Products:

Line Item No.

[List as necessary]

(3) *Buy American Act—Free Trade Agreements—Israeli Trade Act Certificate, Alternate II (Jan 2004)*. If Alternate II to the clause at FAR 52.225-3 is included in this solicitation, substitute the following paragraph (g)(1)(ii) for paragraph (g)(1)(ii) of the basic provision:

(g)(1)(ii) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled “Buy American Act—Free Trade Agreements—Israeli Trade Act”:

Canadian or Israeli End Products:

Line Item No.	Country of Origin
---------------	-------------------

_____	_____
_____	_____
_____	_____

[List as necessary]

(4) *Trade Agreements Certificate*. (Applies only if the clause at FAR 52.225-5, Trade Agreements, is included in this solicitation.)

(i) The offeror certifies that each end product, except those listed in paragraph (g)(4)(ii) of this provision, is a U.S.-made or designated country end product, as defined in the clause of this solicitation entitled “Trade Agreements.”

(ii) The offeror shall list as other end products those end products that are not U.S.-made or designated country end products.

Other End Products:

Line Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary]

(iii) The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American Act. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

(h) *Certification Regarding Debarment, Suspension or Ineligibility for Award (Executive Order 12549)*. (Applies only if the contract value is expected to exceed the simplified acquisition threshold.) The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals—

(1) o Are, o are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency; and

(2) o Have, o have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(3) o Are, o are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses.

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126)*. [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).]

(1) *Listed end products.*

Listed End Product Listed Countries of Origin

(2) *Certification.* [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]

[] (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

[] (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j)(1) *Annual Representations and Certifications.* Any changes provided by the offeror in paragraph (j) of this provision do not automatically change the representations and certifications posted on the Online Representations and Certifications Application (ORCA) website.

(2) The offeror has completed the annual representations and certifications electronically via the ORCA website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212-3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

[Offeror to identify the applicable paragraphs at (b) through (i) of this provision that the offeror has completed for the purposes of this solicitation only, if any.]

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.]

(End of provision)

Alternate I (Apr 2002). As prescribed in 12.301(b)(2), add the following paragraph (c)(11) to the basic provision:

(11) (Complete if the offeror has represented itself as disadvantaged in paragraph (c)(4) or (c)(9) of this provision.)

[The offeror shall check the category in which its ownership falls]:

_____ Black American.

_____ Hispanic American.

_____ Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians).

_____ Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, The Philippines, U.S. Trust Territory of the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).

_____ Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal).

_____ Individual/concern, other than one of the preceding.

Alternate II (Oct 2000). As prescribed in 12.301(b) (2), add the following paragraph (c) (9) (iii) to the basic provision:

(iii) *Address.* The offeror represents that its address is, or is not in a region for which a small disadvantaged business procurement mechanism is authorized and its address has not changed since its certification as a small disadvantaged business concern or submission of its application for certification. The list of authorized small disadvantaged business procurement mechanisms and regions is posted at <http://www.arnet.gov/References/sdbadjustments.htm>. The offeror shall use the list in effect on the date of this solicitation. "Address," as used in this provision, means the address of the offeror as listed on the Small Business Administration's register of small disadvantaged business concerns or the address on the completed application that the concern has submitted to the Small Business Administration or a Private Certifier in accordance with 13 CFR Part 124, subpart B. For joint ventures, "address" refers to the address of the small disadvantaged business concern that is participating in the joint venture.

I.6. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

<u>Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2006	Definitions
352.232-9	Jan 2006	Withholding of Contract Payments
352.270-4	Jan 2001	Pricing of Adjustments
352.270-6	Jan 2006	Publication and Publicity
352.270-7	Jan 2006	Paperwork Reduction Act

I.7. 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders- Commercial Items (Jul 2005)

CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—
COMMERCIAL ITEMS (JULY 2005)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).

(2) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub. L. 108-77, 108-78)

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

 X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sep 2006), with Alternate I (Oct 1995) (41 U.S.C. 253g and 10 U.S.C. 2402).

 (2) 52.219-3, Notice of Total HUB Zone Set-Aside (Jan 1999) (15 U.S.C. 657a).

 (3) 52.219-4, Notice of Price Evaluation Preference for HUB Zone Small Business Concerns (JULY 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

 (4) (i) 52.219-5, Very Small Business Set-Aside (June 2003) (Pub). L. 103-403, section 304, Small Business Reauthorization and Amendments Act of 1994).

 (ii) Alternate I (Mar 1999) of 52.219-5.

 (iii) Alternate II (June 2003) of 52.219-5.

 (5) (i) 52.219-6, Notice of Total Small Business Set-Aside (June 2003) (15 U.S.C. 644).

 (ii) Alternate I (Oct 1995) of 52.219-6.

 (iii) Alternate II (Mar 2004) of 52.219-6.

 (6) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).

 (ii) Alternate I (Oct 1995) of 52.219-7.

 (iii) Alternate II (Mar 2004) of 52.219-7.

- ☒ (7) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d) (2) and (3).
- ☐ (8) (i) 52.219-9, Small Business Subcontracting Plan (Nov 2007) (15 U.S.C. 637(d) (4).
- ☐ (ii) Alternate I (Oct 2001) of 52.219-9.
- ☐ (iii) Alternate II (Oct 2001) of 52.219-9.
- ☐ (9) 52.219-14, Limitations on Subcontracting (Dec 1996) (15 U.S.C. 637(a) (14).
- ☐ (10) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (SEP 2005) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).
- ☐ (ii) Alternate I (June 2003) of 52.219-23.
- ☐ (11) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (Oct 1999) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).
- ☐ (12) 52.219-26, Small Disadvantaged Business Participation Program—Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).
- ☐ (13) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (May 2004).
- ☒ (14) 52.222-3, Convict Labor (June 2003) (E.O. 11755).
- ☒ (15) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (Aug 2007) (E.O. 13126).
- ☒ (16) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).
- ☒ (17) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).
- ☒ (18) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001) (38 U.S.C. 4212).
- ☒ (19) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998) (29 U.S.C. 793).
- ☒ (20) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006) (38 U.S.C. 4212).
- ☐ (21) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).
- ☐ (22) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Aug 2000) (42 U.S.C. 6962(c) (3) (A) (ii)).
- ☐ (ii) Alternate I (Aug 2000) of 52.223-9 (42 U.S.C. 6962(i) (2) (C)).
- ☐ (23) 52.225-1, Buy American Act—Supplies (June 2003) (41 U.S.C. 10a-10d).
- ☐ (24) (i) 52.225-3, Buy American Act—Free Trade Agreements—Israeli Trade Act (Aug 2007) (41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, Pub. L. 108-77, 108-78, 108-286).
- ☐ (ii) Alternate I (Jan 2004) of 52.225-3.
- ☐ (iii) Alternate II (Jan 2004) of 52.225-3.
- ☐ (25) 52.225-5, Trade Agreements (Nov 2007) (19 U.S.C. 2501, *et seq.*, 19 U.S.C. 3301 note).
- ☐ (26) 52.225-13, Restrictions on Certain Foreign Purchases (Feb 2006) (E.o.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- ☐ (27) 52.225-15, Sanctioned European Union Country End Products (Feb 2000) (E.O. 12849).

- ___ (28) 52.225-16, Sanctioned European Union Country Services (Feb 2000) (E.O. 12849).
- ___ (29) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
- ___ (30) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
- _X_ (31) 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration (Oct 2003) (31 U.S.C. 3332).
- ___ (32) 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration (May 1999) (31 U.S.C. 3332).
- ___ (33) 52.232-36, Payment by Third Party (May 1999) (31 U.S.C. 3332).
- ___ (34) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- ___ (35) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App. 1241 and 10 U.S.C. 2631).
- ___ (ii) Alternate I (Apr 2003) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

- ___ (1) 52.222-41, Service Contract Act of 1965, as Amended (Nov 2007) (41 U.S.C. 351, *et seq.*).
- ___ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).
- ___ (3) 52.222-43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (Nov 2006) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).
- ___ (4) 52.222-44, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Feb 2002) (29 U.S.C. 206 and 41 U.S.C. 351, *et seq.*).
- ___ (5) 52.222-47, SCA Minimum Wages and Fringe Benefits Applicable to Successor Contract Pursuant to Predecessor Contractor Collective Bargaining Agreements (CBA) (May 1989) (41 U.S.C. 351, *et seq.*).

(d) *Comptroller General Examination of Record.* The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising

under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (i) through (vii) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d) (2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246).

(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006) (38 U.S.C. 4212).

(iv) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793).

(v) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201).

(vi) 52.222-41, Service Contract Act of 1965, as Amended (Nov 2007), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, *et seq.*).

(vii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App. 1241 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

Attachments:

Invoice Instructions for Fixed Price Contracts, Attachment 1
Technical Proposal Instructions, Attachment 2

ATTACHMENT 1

INVOICE INSTRUCTIONS FOR FIXED-PRICE CONTRACTS.

General The contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form 1035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, or the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

- (a) Designated Billing Office and address:

HHS/ASPR/BARDA
330 Independence Ave SW, G640,
Washington, DC 20201
ATTN: Contract Specialist

- (b) Invoice Number

- (c) Date of Invoice

- (d) Contract number and date

(e) Payee's name and address. Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than \$25, attach prepaid bill.)

(h) Equipment If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of

gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ATTACHMENT 2

TECHNICAL PROPOSAL INSTRUCTIONS

The technical discussion included in the technical proposal should respond to the items set forth below:

- (1) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's statement of work will not be eligible for award. The technical proposal should contain an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- (2) A detailed work plan must be submitted indicating how much each aspect of the statement of work is to be accomplished. This plan should be in as much detail as considered necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken.
- (3) The technical proposal must include information on how the project is to be organized, staffed, and managed. This information should demonstrate your understanding of important events or tasks and their management. You must explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished.
- (4) The technical proposal must describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

The Statement of Objectives (SOO), included as Section C2 above, provides the Government's overall objectives for this solicitation. Offerors shall use the SOO, together with other applicable portions of this RFP, as the basis for preparing their proposal, including the SOW. The offeror shall ensure all aspects of the SOO are addressed. The SOW should specify in clear, understandable terms the work to be done in developing or producing the goods to be delivered or services to be performed by the contractor. Preparation of an effective SOW requires both an understanding of the goods or services that are needed to satisfy a particular requirement and an ability to define what is required in specific, performance based, and quantitative terms. The offeror's understanding of both required goods/services and work effort required to accomplish the objectives should be fully demonstrated in the offeror's proposed SOW. For complex inter-relationships among RFP/contract documents, use of a cross-reference matrix may be helpful.

The Offeror is instructed to respond to this solicitation in the following manner:

- (a) Provide rationale for the use of up to ten foodstuffs, drinks, or other human ingestibles (may include condiments) that may be used as a vehicle for doxycycline and ciprofloxacin drug products, respectively. Provide supporting data from the peer-reviewed literature, and/ or theoretical arguments, for how the proposed comestibles may be used to carry drug and its respective excipient matrix without inhibiting its known pharmacokinetic / ADME properties. Propose arguments based on digestibility of the comestible. Provide rationale for the design and interpretation of palatability

studies that measure taste-masking of the drug product matrix. Provide rationale and description for the metric proposed by the Offeror to quantitate palatability. Propose potential contractor partners (if any) that the Offeror intends to use to conduct palatability studies.

- (b) Propose a preparation instruction set describing the preparation of the respective drug product and the food / drug mixture for each of the respective foodstuffs proposed by the Offeror. Propose an instruction set that can be read by users with a basic command of vernacular American English. Provide proposed instructions that can be readily translated into Spanish and French. Propose a kit format to contain instructions and/or tools/equipment necessary to compound drug product with foodstuffs. Include proposed contractor partners (if any) that the Offeror intends to use to manufacture, print, and/or distribute the kit format and its contents.

The technical proposal must be prepared and submitted in a format to facilitate proposal evaluation. The technical proposal should be in a 12-pitch type and printed single-sided on 8.5 by 11 inch paper.

The proposal should contain a separate section addressing:

1. The offeror's understanding of the methodology and technical approach
2. The offeror's management plan and personnel
3. The offeror's facilities.

Additional Business Proposal Instructions

The cost proposal is to be submitted as a separate document from the technical quotation. The cost proposal shall be specific and sufficient in detail in order that a reviewer of the information would require a minimum of exchanges with the preparer of the information.

The direct labor hour mix and personnel proposed as part of the cost proposal shall be the same as proposed in the technical proposal.

For evaluation purposes, vendors are required to propose the other direct costs identified in the solicitation for the quantity of the base period and option period. The vendors shall provide an estimate of the travel costs, including transportation, lodging, meals, and incidental expenses, that are expected to be incurred in performance of the SOO.